WRIGHT

FEB 2 7 2006

K060011

510(k) SUMMARY
OF SAFETY AND EFFECTIVENESS

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CRF 807, this information serves as a Summary of Safety and Effectiveness for the use of MIIG® SR.

Submitted By:	Wright Medical Technology, Inc.
Date:	December 30, 2005
Contact Person:	Brian J. Young Sr. Director, Regulatory Affairs Phone: 901-867-4120 Fax: 901-867-4630
Proprietary Name:	**MIIG® SR**
Common Name:	Bone Void Filler
Classification Name and Reference:	21 CFR 888.3045, Resorbable Calcium Salt Bone Void Filler Device
Device Product Code and Panel Code:	Orthopedics/87/MQV

DEVICE INFORMATION

A. INTENDED USES/ INDICATIONS

The intended use for the MIIG® SR resultant paste is to be injected, digitally packed into open bone voids/gaps to cure in-situ, or molded into solid pellets that are gently packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities, spine, and pelvis). These open bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste/pellets provide a bone void filler that resorbs and is replaced with bone during the healing process.

The MIIG® SR paste cured in situ provides an open void/gap filler that can augment provisional hardware (e.g. K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

MIIG® SR is provided sterile for single use only.

B. DEVICE DESCRIPTION

MIIG SR® bone void filler is supplied in paste and powder forms. MIIG® SR consists of a calcium sulfate/calcium phosphate composite bone void filler along with instruments for mixing and delivering the graft to the defect site.

C. MATERIALS

MIIG® SR bone void filler is comprised of calcium sulfate and calcium phosphate. As such, MIIG® SR bone void filler is substantially equivalent to other predicate 510(k) cleared Wright Medical Technology products. The resultant powder is diluted with an aqueous solution comprised of the same USP sterile water used in a predicate WMT bone void filler and combined with high purity glycolic acid titrated with sodium hydroxide to a neutral pH.

D. SUBSTANTIAL EQUIVALENCE INFORMATION

The intended use, material composition, and design features of the MIIG® SR are substantially equivalent to previously cleared 510(k) WMT bone void fillers. The safety and effectiveness of MIIG® SR is adequately supported by the substantial equivalence information, materials data, compliance with the FDA guidance document[1], and biocompatibility testing results provided within this Premarket Notification.

[1] Class II Special Controls Guidance Document: Resorbable Calcium Salt Bone Void Filler Device; Guidance for Industry and FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 27 2006

Mr. Brain J. Young
Sr. Director, Regulatory Affairs
Wright Medical Technology, Inc.
5677 Airline Road
Arlington, TN 38002

Re: K060011
Trade/Device Name: MIIG®SR
Regulation Number: 21 CFR 888.3045
Regulation Name: Bone Void Filler
Regulatory Class: II
Product Code: MQV
Dated: December 30, 2005
Received: January 03, 2006

Dear Mr. Young:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120 . Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

for Mark N. Melkerson
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

WRIGHT.
TM

Indications for Use Statement

510(k) Number: Not yet assigned.

Device Name: MIIG® SR

Indications For Use:

The intended use for the MIIG® SR resultant paste is to be injected, digitally packed into open bone voids/gaps to cure in-situ, or molded into solid pellets that are gently packed into open bone voids/gaps that are not intrinsic to the stability of bony structure of the skeletal system (i.e., the extremities, spine, and pelvis). These open bone voids may be surgically created osseous defects or osseous defects created from traumatic injury to the bone. The paste/pellets provide a bone void filler that resorbs and is replaced with bone during the healing process.

The MIIG® SR paste cured in situ provides an open void/gap filler that can augment provisional hardware (e.g. K-Wires) to help support bone fragments during the surgical procedure. The cured paste acts only as a temporary support media and is not intended to provide structural support during the healing process.

MIIG® SR is provided sterile for single use only.

(Division Sign-Off)

Division of General Restorative Devices

510(k) Number _____

Prescription Use ✓ OR Over-The Counter Use ____
(Per21 CFR 801.109) (Optional Format 1-2-96)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Office of CDRH, Office of Device Evaluation (ODE)

510(k) Number K060011

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